MEMO ENDORSED

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August 11, 2008

VIA HAND-DELIVERY

Honorable Denise L. Cote
United States District Judge
United States District Court for the
Southern District of New York
500 Pearl Street, Room 1040
New York, New York 10007

Re: *Takeda Pharmaceutical Company Limited et al. v. Mylan, Inc. et al.*, Civil Action No. 08 CV 6999 (S.D.N.Y.)

Dear Judge Cote:

Your Honor previously received a letter to the Honorable Kimba Wood objecting to the Plaintiffs' related case designation from Mylan, Inc., Mylan Pharmaceuticals, Inc. and UDL Laboratories, Inc. (collectively, "Mylan"), Defendants in the above-referenced litigation filed on or about August 6, 2008 ("the Current Litigation"). We understand that your Honor will decide whether to accept Plaintiffs' related case designation. We write to provide further information on the Current Litigation and to reiterate Mylan's position objecting to the Plaintiffs related case designation.

Plaintiffs have designated the Current Litigation as related to a civil case already pending before the Court, namely, Civil Action No. 03 CV 8253 pending before Your Honor ("the already-pending litigation"). Mylan respectfully objects to Plaintiffs' related-case designation, and in particular the suggestion that the Court could conserve judicial resources or advance the litigation more efficiently or economically by deeming these cases related for purposes of judicial assignment.

Based on Plaintiffs' Complaint, the issues in the Current Litigation will revolve around, among other things, the following circumstances:

- A prescription anti-diabetic medicine, pioglitazone hydrochloride and metformin hydrochloride, that Takeda sells as one medicine under the trade-name Actoplus Met™ Tablets 15 mg/500 mg and 15 mg/850 mg.

- New Drug Application ("NDA") No. 21-842, under which the U.S. Food and Drug Administration ("FDA") first approved Actoplus Met™ (pioglitazone HCL and metformin HCL) Tablets 15 mg/500 mg and 15 mg/850 mg to Takeda Global Research & Development Center, Inc. on August 29, 2005.

- Mylan's recently-filed Abbreviated New Drug Application ("ANDA") No. 90-406, under which Mylan seeks to market a generic form of Actoplus Met™ Tablets 15 mg/500 mg and 15 mg/850 mg product.

On the other hand, the already-pending litigation involves, among others, the following circumstances:

- A different, single prescription anti-diabetic medicine, pioglitazone hydrochloride, that Takeda sells under the trade name Actos™ Tablets 15 mg, 30 mg and 45 mg;

- A different NDA, NDA No. 21-073, under which FDA first approved Actos™ (pioglitazone hydrochloride) Tablets 15 mg, 30 mg and 45 mg to Takeda America Research & Development Center, Inc. on July 15, 1999;

- A different ANDA, Mylan's ANDA No. 76-801, under which Mylan seeks to market a generic form of Actos™ Tablets, 15 mg, 30 mg and 45 mg.

Thus, these actions clearly involve (i) entirely different brand drug products, (ii) entirely different ANDAs; and (iii) entirely different NDAs. Relevant discovery, including written discovery and expert witnesses, and defenses to the asserted claims in the Current Litigation will necessarily need to be specifically tailored based on the circumstances of that particular Litigation. As such, it is reasonable to anticipate that the claim construction, infringement analysis, defenses, witnesses, document discovery and fact and expert discovery in the Current Litigation will necessarily diverge from that in the already-pending litigation. For example, the most basic of elements relevant to the Current Litigation will be different, including as noted above, the relevant NDA and accused ANDA product.

Given these differences, assigning the Current Litigation as a "related case" to the already-pending litigation will likely not (i) conserve judicial resources, (ii) advance efficient and economical conduct of the litigations, nor (iii) serve the convenience of the parties and witnesses, and therefore cannot serve as a "related" case as contemplated under the related case provisions of the Local Civil Rules, including under Rule 15 of the Rules for the Division of Business Among District Judges. This is true even though the patents at issue in the Current Litigation may be the same as some of those in the already-

pending litigation because the analysis of those patents will be different in light of the circumstances described above.

Notably, the five previously filed actions (only one of which involves Mylan) to which Plaintiffs refer in their Civil Cover Sheet in support of their "related" case designation involved the **exact** same NDA and drug products and as a result similar issues. Such is not the case here for the reasons described above. Moreover, discovery is already complete in those previously filed actions. As such, judicial resources will not be conserved since the parties will need, and in fact have the right, to conduct thorough discovery in the Current Litigation that, again, will be separate and apart from that in the already-pending litigation. Mylan notes as well that the Current Litigation involves a different thirty-month stay period, which fact just further highlights the distinguishing factors between these litigations that undermine their "relatedness" for judicial assignment purposes.

Mylan therefore respectfully objects to Plaintiffs' related case designation and requests that your Honor not consider the Current Litigation as related to the already-pending litigation.

Respectfully submitted,

Thomas J. Parker

cc: Anthony J. Viola, Attorney for Plaintiffs (via facsimile)
David G. Conlin, Attorney for Plaintiffs (via facsimile)
William A. Rakoczy, Attorney for Defendants (via facsimile)

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The remaining parties to this litigation shall respond with their positions by letters submitted by August 15 at noon.

Denise Cote
August 12, 2008